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EXAMINER	
MYERS, CARLA J	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,213	PRICE, SUZANNE MARGARET	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6,9,12,13 and 15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-6, 9, 12, 13, and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the reply of March 23, 2009. Applicant's arguments and amendments to the claims have been fully considered but are not persuasive to place all claims in condition for allowance. All rejections not reiterated herein are hereby withdrawn. In particular, the rejection of claims 1-2, 5, 6, 7, 8, 9, 12, 13 and 15-19 under 35 U.S.C. 102(b) as being anticipated by Miwa (U.S. Patent No. 4,514,502) has been obviated by the amendment to the claims to recite a step of "contacting the sample with a nucleic acid probe that preferentially binds to the contaminating nucleic acids originating from the site and renders them removable from the sample."

2. Claims 1-2, 4-6, 9, 12, 13, and 15-19 are pending and have been examined herein. It is noted that the claims have been examined only to the extent that the claim read on the elected invention of methods wherein the pretreatment is an enzymatic pretreatment.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 13 and 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite over the recitation of “which further comprises PCR…” because it is not clear as to how this recitation is intended to further limit the claim. It is

unclear as to what is meant by a method comprising a method, such as PCR. For example, it is unclear as to whether claim 12 is intended to be limited to methods which further comprise performing PCR, mitochondrial DNA sequence, single nucleotide polymorphism analysis or low copy number PCR, or whether the method of claim 1 is a method of PCR etc. The recitation in claim 12 of a method that further comprises PCR etc does not constitute an active process step and thereby it is unclear as to how this recitation is intended to further limit the method of claim 1.

Claims 13 and 15-18 are indefinite over the recitation of "the pre-treatment step of removing cell bound contaminating nucleic acids" because this phrase lacks proper antecedent basis since claim 1 does not recite a step of pre-treatment to remove cell bound contaminating nucleic acids. Further, it is unclear as to how this limitation is intended to further limit the method of claim 1 since claim 1 already recites a step of contacting the sample with a probe. It is unclear, for example, if claims 13 and 15-18 are intended to include a second, separate step of contacting the sample with the same or a different probe or are intended to in some unspecified manner further define step ii of claim 1 of contacting the sample with a probe.

Claim 19 is indefinite over the recitation of "the pre-treatment steps comprise removing cell bound contaminating nucleic acids from the sample by exposing nucleic acids in the cells and then removing the nucleic acids" because this phrase lacks proper antecedent basis since claim 1, from which claim 19 depends, does not recite any pre-treatment steps. Accordingly, it is unclear as to how this recitation is intended to further limit the claims.

Maintained Rejections

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-6, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker (EP 0585660; cited in the IDS).

The following grounds of rejection were previously presented in the Office action of September 19, 2008 and have been modified herein to address the amendments to the claims.

Walker teaches a method for analyzing a nucleic acid sample obtained from a site wherein the method comprises: i) pretreating the nucleic acid sample with a single-strand specific exonuclease to remove or inactivate contaminating nucleic acids obtained from the site; ii) contacting the sample with a primer (which is also considered to be a probe) which preferentially binds to contaminating nucleic acids originating from the site; and iii) amplifying the pretreated sample to thereby analyze the nucleic acid sample (see, e.g., page 2, lines 24-57 and page 4, lines 43-46). In the method of Walker, the step of treating the nucleic acid sample with a single-strand specific exonuclease constitutes a step of pretreating the sample. Further, the method of Walker is one in which the pretreatment preferentially removes or inactivates nucleic acids

produced by other amplification processes and thereby removes or inactivates nucleic acids that are free or substantially free of other cell components.

Regarding step ii) of the present claims, in the method of Walker, the exonuclease digested nucleic acids are contacted with amplification primers (e.g., page 4, lines 28-30 and 54-57). As taught by Walker, the primers have the property of hybridizing to the contaminating amplicon nucleic acids. Note that the present claims do not recite any structural features that would distinguish a nucleic acid primer over a nucleic acid probe. Thereby, the method of Walker is considered to be one that contacts the sample with a nucleic acid probe. The primer/probe of Walker preferentially binds to contaminating amplicon sequences and does not bind to non-target sequences that are different from those present in the amplicon. Thereby the primer/probe of Walker preferentially binds to the contaminating nucleic acids (i.e., the amplicons) and does not bind to non-target sequences that are different from the amplicon sequences. Note that the present claims do not define what constitutes "preferentially binds" and in particular do not set forth what the primer/probe does not bind to and thereby preferential binding may include binding to the contaminating nucleic acids and binding to a lesser degree to any other unspecified nucleic acid. Binding of the primer/probe of Walker to contaminating nucleic acids is considered to "render them removable from a sample" because the hybridized contaminating nucleic acids could be removed by digestion with enzymes that cleaves double-stranded DNA or could be removed by binding to an immobilized capture probe that would permit removing bound hybridized contaminating nucleic acids from the sample solution. It is noted that the claims broadly recite only that

the contaminating nucleic acids are rendered "removable." The claims do not require performing any type of an active process step of removing the contaminating nucleic acids bound to the primer/probe.

Regarding the recitation that the contaminating nucleic acids were purposefully added to the sample, Walker teaches that 1000 amplicons (i.e., contaminating nucleic acids) were added to the sample. The addition of the 1000 amplicons would serve to confound future analysis of target nucleic acids present in the sample. Further, it is noted that the recitation of why the contaminating nucleic acids are present in the sample (i.e., for the intention of confounding future analysis of target nucleic acids) is a mental step and thereby is not considered to materially limit the claims, or distinguish the claims over the method of Walker.

Additionally, in the method of Walker, the sample is contaminated with laboratory derived nucleic acids. This type of nucleic acid meets the limitations of the claims since such a nucleic has been introduced into the sample in the laboratory and confounds future analysis of the sample. Again, the intention behind why the nucleic acid is present in the sample is a mental concept and does not materially limit the claims. The claims do not recite an active process step of adding a contaminating nucleic acid to a sample and/or do not recite any additional active process steps which distinguish the claims over the method of Walker. The method of Walker includes each of the active process steps of the present claims, and thereby anticipates the present claims, since Walker also teaches a method comprising pretreating a sample prior to analysis to remove or

inactivate contaminating laboratory nucleic acids present in the sample which confound future analysis of target nucleic acids present in the sample.

Regarding claim 2, in the method of Walker, the nucleic acid is DNA (see, e.g., page 4, lines 3-15 and Example 2).

Regarding claim 4, Walker teaches that the contaminating nucleic acid may be an amplicon from a previous PCR (see, e.g. page 2, lines 7-13).

Regarding claim 5, the contaminating nucleic acid is considered to be degradation resistant since DNA is substantially more stable than other molecules and is resistant to many enzymes, such as RNases.

Regarding claim 6, the contaminating nucleic acid is considered to be synthetic since nucleic acids that have been synthesized by some process such as an amplification process constitute synthetic nucleic acids.

Regarding claim 9, the pretreatment step of Walker comprises treating the nucleic acid sample using an exonuclease (page 2, lines 24-30).

Regarding claim 12, Walker (page 2, lines 40-53) teaches that following the pretreatment step, the nucleic acid sample may be analyzed by any amplification method, including the method of PCR.

Response to Remarks:

In the response, Applicant's traversed this rejection by stating that " the methods described in the Walker patent would be detrimental to the detection and/or removal of amplicon contamination where the DNA profile was determined by the use of single nucleotide polymorphisms as used in forensic studies as per the present application.

This is because the conditions required to reliably degrade any contaminating amplicons as described in the Walker patent would also invariably completely degrade any sample nucleic acids, again rendering the determination of a valid DNA profile impossible." Applicants thereby conclude that Walker teaches away from the claimed invention.

These arguments have been fully considered but are not persuasive because they are directed to limitations that are not recited in the claims. The claims are not directed to methods of using SNP analysis for forensic studies. Nor do the present claims exclude in any manner a method of treating a sample with exonuclease, as taught by Walker. In fact, claim 9 specifically requires the use of an exonuclease to treat the sample.

Applicants state that if the method of Walker were used for the "purposes of the present invention," the target nucleic acid and contaminating nucleic acid would both be degraded. This argument is not persuasive because the present claims do not define the source or identity of the "target nucleic acid" and thereby do not recite any limitations which distinguish the claimed method over that of Walker. Applicants are reminded that, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants assert that Walker teaches cleaving small amplicons. It is stated that target nucleic acids of forensic interest are often degraded and would be 200-500bp and thereby would be preferentially degraded along with contaminating nucleic acids in the

method of Walker. This argument is not persuasive. Again, the present claims are not directed to a method of treating a forensic sample. Nor are the claims limited to methods of enzymatically removing contaminating nucleic acids of any particular length. There are no limitations in the claims which require that the target nucleic acid is of a particular length or that the contaminating nucleic acid of a particular length. The claims also do not require performing any particular type of enzymatic cleavage, particularly with the exonuclease required by claim 9, which would permit the preferential cleavage of only contaminating nucleic acids and would not result in cleavage of a target nucleic acid of 200-500bp.

Applicants state that the claims have been amended to recite a step of "contacting the sample with a nucleic acid probe that preferentially binds to the contaminating nucleic acids originating from the site and renders them removable from the sample." Applicants assert that Walker does not teach this limitation.

This argument has been fully considered but is not persuasive. As set forth in the above rejection, Walker teaches that the exonuclease digested nucleic acids are contacted with amplification primers (e.g., page 4, lines 28-30 and 54-57). As taught by Walker, the primers have the property of hybridizing to the contaminating amplicon nucleic acids. Note that the present claims do not recite any structural features that would distinguish a nucleic acid primer over a nucleic acid probe. Also, the specification does not provide a limiting definition for the term "probe" which distinguishes "probes" from "primers" or from any other type of nucleic acid. Thereby, the method of Walker is considered to be one that contacts the sample with a nucleic acid probe. The

primer/probe of Walker preferentially binds to contaminating amplicon sequences and does not bind to non-target sequences that are different from those present in the amplicon. Thereby the primer/probe of Walker preferentially binds to the contaminating nucleic acids (i.e., the amplicons) and does not bind to non-target sequences that are different from the amplicon sequences. Note that the present claims do not define what constitutes “preferentially binds” and in particular do not set forth what the primer/probe does not bind to and thereby preferential binding may include binding to the contaminating nucleic acids and binding to a lesser degree to any other unspecified nucleic acid. Binding of the primer/probe of Walker to contaminating nucleic acids is considered to “render them removable from a sample” because the hybridized contaminating nucleic acids could be removed by digestion with enzymes that cleaves double-stranded DNA or could be removed by binding to an immobilized capture probe that would permit removing bound hybridized contaminating nucleic acids from the sample solution. It is noted that the claims broadly recite only that the contaminating nucleic acids are rendered "removable." The claims do not require performing any type of an active process step of removing the contaminating nucleic acids bound to the primer/probe.

Applicants state that the method of Walker does not remove all 10,000 amplicon molecules from samples following treatment with 15 units of exonuclease. Applicants conclude that the method of Walker is not effective at removing large numbers of contaminating amplicons. This argument has also been fully considered but is not persuasive. First, the present claims do not require that the “enzymic treatment”

removes all contaminating nucleic acids and therefore Applicant's arguments are directed to limitations that are not recited in the claims. In fact, the present claims specifically permit methods in which the enzymic treatment does not remove all contaminating nucleic acids because the claims require treating with a probe that renders contaminating nucleic acids removable, following the enzymic treatment step. Secondly, the claims do not require that the contaminating nucleic acid is present at any particular level, such as a level of above 100,000 amplicons. The claims do not require that the enzymic treatment step accomplishes any particular level of removal of the contaminating nucleic acids. Applicants have not established that the claimed invention provides any improved results over those obtained by Walker. The present claims do not recite any particular enzymes used for treatment or any particular conditions of treatment and thereby the claimed methods cannot be fairly compared to the method of Walker. However, it is noted that present specification does not exemplify any methods in which all amplicons are removed from a sample and the sample is subsequently used for forensic analysis. In fact, the specification (page 19) teaches:

> With the exception of DNAse (mixture + DNAse) the treatments trialled to remove the contaminating microsatellite PCR products failed to have any significant effect on the level of contaminant amplified during subsequent amplification for cat GD450 microsatellite loci. In the sample treated with DNAse I, however, the microsatellite contaminant was efficiently removed since no detectable cat MV5 bands were present following PCR amplification for cat GD450 microsatellite loci (mixture + DNAse I, I#L and 5pL samples). However, there was also an absence of GD450 bands suggesting that the treatment used also completely removed genomic DNA from the sample.
>
> This result demonstrated that the removal of contaminating microsatellite PCR products from tissue is possible. However, it is not easily achieved by either physical or chemical methods that are frequently used to remove contaminating DNA. It also showed that the complete removal of contaminating microsatellite

> PCR products requires additions/modifications to both reagents and protocols in DNA extraction methods often used for DNA fingerprinting studies. DNAse I was effective at removing contaminating microsatellite PCR products but the method used in this study is not suitable for inclusion in a DNA extraction kit.

Thereby, it is unclear as to how Applicants comments regarding the effectiveness of the exonuclease treatment method of Walker are intended to distinguish the claimed invention over that of Walker since the present claims do not require achieving any particular level of removal/inactivation of contaminating nucleic acids and the present specification does not exemplify any methods that remove all contaminating amplicons from a sample, prior to the effective forensic analysis of the sample. It is also again noted that while the specification may provide examples and may discuss preferred embodiments, these teachings are not read as limitations into the claims. The present claims broadly encompass general methods of treating any type of sample with any enzymic treatment, under any conditions, to remove or inactivate any level of any contaminating nucleic acid. The present claims do not recite any limitations that distinguish the claimed methods over the method of Walker.

5. Claims 1, 2, 4-6, 9, 12, 13 and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Satishchandran et al (U.S. Patent No. 6,168,918).

The following grounds of rejection were previously presented in the Office action of September 19, 2008 and have been modified herein to address the amendments to the claims.

Satishchandran teaches a method for analyzing a nucleic acid sample obtained from a site wherein the method comprises: i) treating the nucleic acid sample with DpnI restriction endonuclease to remove to remove or inactivate contaminating plasmid

nucleic acids present in the sample; and ii) contacting the sample with a nucleic acid primer (which is also considered to be a nucleic acid probe), wherein the nucleic acid primer/probe binds to contaminating nucleic acids that originate from the site; and iii) analyzing the pretreated nucleic acid sample (see, e.g., col. 5, lines 29-67; col. 7, lines 28-67). In the method of Satishchandran, the step of treating the nucleic acid sample with DpnI restriction endonuclease constitutes a step of pretreating the sample to remove or inactivate contaminating bacterial plasmid DNA. Further, the treatment with DpnI occurs after lysis of the cells and isolation of nucleic acids to remove cellular components (e.g., col. 17, line 48 to col. 18, line 30). Thereby, the treatment comprises treating the sample with DpnI to remove nucleic acids (plasmid DNA) that are substantially free from other cell components.

Regarding step ii) of the present claims, in the method of Satishchandran, the DpnI digested nucleic acids are contacted with PCR primers. The present claims do not recite any structural features that would distinguish a nucleic acid primer over a nucleic acid probe. Thereby, the method of Satishchandran is considered to be one that contacts the sample with a nucleic acid probe. The primer/probe of Satishchandran preferentially binds to plasmid DNA at sequences flanking the DpnI sites (col. 12, lines 32-41). Thereby the primer/probe of Satishchandran preferentially binds to the contaminating nucleic acids (i.e., the non-integrated plasmids) and does not bind to eukaryotic sequences. Note that the present claims do not define what constitutes “preferentially binds” and in particular do not set forth what the primer/probe does not bind to and thereby preferential binding may include binding to the contaminating

nucleic acids and binding to a lesser degree to any other unspecified nucleic acid. Binding of the primer/probe of Satishchandran to contaminating nucleic acids is considered to “render them removable from a sample” because the hybridized contaminating nucleic acids could be removed by digestion with enzymes that cleave double-stranded DNA or could be removed by binding to an immobilized capture probe that would permit removing bound hybridized contaminating nucleic acids from the sample solution. It is noted that the claims broadly recite only that the contaminating nucleic acids are rendered "removable." The claims do not require performing any type of an active process step of removing the contaminating nucleic acids bound to the primer/probe.

Regarding the recitation that the contaminating nucleic acid is purposefully introduced to the sample to confound future analysis of target nucleic acids in the sample, in the method of Satishchandran, the contaminating plasmid DNA is purposefully introduced into eukaryotic cells prior to the analysis of the cells. It is a property of the plasmid DNA that its presence would confound future analysis of target chromosomal nucleic acids present in a sample. Further, it is noted that the recitation of why the contaminating nucleic acids are present in the sample (i.e., for the intention of confounding future analysis of target nucleic acids) is a mental step and thereby is not considered to materially limit the claims, or distinguish the claims over the method of Satishchandran. The claims do not recite an active process step of adding a contaminating nucleic acid to a sample and/or do not recite any additional active process steps which distinguish the claims over the method of Satishchandran. The

method of Satishchandran includes each of the active process steps of the present claims, and thereby anticipates the present claims, since Satishchandran also teaches a method comprising pretreating a sample prior to analysis to remove or inactivate contaminating plasmid DNA introduced into the sample which confounds future analysis of target chromosomal nucleic acids present in the sample.

Regarding claim 2, in the method of Satishchandran, the contaminating nucleic acid present in the sample is DNA (see, e.g., col. 7, lines 30-34).

Regarding claim 4, the contaminating plasmid DNA is a nucleic acid derived from "another DNA amplification process" since plasmid DNA is produced by replication in a cell (i.e., replication is considered to be a process of amplification since copies of plasmid DNA are produced).

Regarding claim 5, the contaminating plasmid DNA is considered to be degradation resistant since plasmid DNA is resistant to many enzymes, such as RNases.

Regarding claim 6, the contaminating nucleic acid is considered to be synthetic since plasmid DNA present in a cell has been synthesized.

Regarding claim 9, the pretreatment step of Satishchandran comprises treating the nucleic acid sample using the enzyme DpnI which is a restriction endonuclease (e.g., col. 1, lines 43-56; col. 4, lines 58-65).

Regarding claim 12, Satishchandran teaches analysis of the pre-treated samples by PCR (col. 8, line 60 through col. 9, line 9).

Regarding claims 13 and 15-19, Satishchandran (e.g., col. 17, line 48 to col. 18, line 30; claims 12 and 18) teaches that the cell is first lysed prior to treatment with DpnI. Accordingly, the pretreatment steps of Satishchandran includes removing cell bound nucleic acids from a cell by exposing the nucleic acids in the cells using a lysing procedure and then removing or inactivating the contaminating plasmid DNA using a DpnI pretreatment step.

Regarding claim 15, the contaminating plasmid DNA is of bacterial origin since it is present in a bacterial cell (e.g., col. 14 lines 53-60).

Regarding claim 16, in the method of Satishchandran, the bacterial cell from which the plasmid is derived has been engineered to carry a multicopy plasmid containing at least one amplicon (i.e., copies of DNA produced by natural amplification/replication of the plasmid; see, e.g., col. 13, lines 3-5; col. 14 lines 53-60).

Response to Remarks:

In the response of March 23, 2009, Applicants state that the claims have been amended to recite a step of "contacting the sample with a nucleic acid probe that preferentially binds to the contaminating nucleic acids originating from the site and renders them removable from the sample." Applicants assert that Satishchandran does not teach this limitation.

This argument has been fully considered but is not persuasive. As set forth in the above rejection, Satishchandran teaches that following DpnI digestion, the sample is contacted with a nucleic acid primer (which is also considered to be a nucleic acid "probe"), wherein the nucleic acid primer/probe binds to contaminating nucleic acids that

originate from the site. The present claims do not recite any structural features that would distinguish a nucleic acid primer over a nucleic acid probe, nor does the specification providing a limiting definition for the term “probe” which distinguishes “probes” from “primers” or from any other type of nucleic acid. Thereby, the method of Satishchandran is considered to be one that contacts the sample with a nucleic acid probe. The primer/probe of Satishchandran preferentially binds to plasmid DNA at sequences flanking the DpnI sites (col 4, lines 51-53; col. 12, lines 32-41). Thereby the primer/probe of Satishchandran preferentially binds to the contaminating nucleic acids (i.e., the non-integrated plasmids) and does not bind to eukaryotic sequences. Note that the present claims do not define what constitutes “preferentially binds” and in particular do not set forth what the primer/probe does not bind to and thereby preferential binding may include binding to the contaminating nucleic acids and binding to a lesser degree to any other unspecified nucleic acid. Binding of the primer/probe of Satishchandran to contaminating nucleic acids is considered to “render them removable from a sample” because the hybridized contaminating nucleic acids could be removed by digestion with enzymes that cleave double-stranded DNA or could be removed by binding to an immobilized capture probe that would permit removing bound hybridized contaminating nucleic acids from the sample solution. It is noted that the claims broadly recite only that the contaminating nucleic acids are rendered "removable." The claims do not require performing any type of an active process step of removing the contaminating nucleic acids bound to the primer/probe.

The response further asserts that the present application addresses the contamination of forensic nucleic acid samples. This argument is not persuasive because the present claims are not directed to methods of removing contaminating nucleic acids from any particular type of forensic sample. For instance, the claims do not define what constitutes the sample, the site from which the sample is derived, the types of nucleic acids present in the sample (other than the contaminating nucleic acids in general). Nor do the claims require performing any particular type of forensic analysis on the pre-treated, treated or untreated sample.

Applicants assert that DpnI sites are not relevant in forensic analysis. It is stated that microsatellite markers, known as STRs, are used in forensic analysis. Applicants assert that forensic STRs do not contain DpnI sites. These arguments have also been fully considered but are not persuasive. Firstly, Applicant's arguments are not persuasive because Applicants do not provide any evidence to establish that contaminating DNA from forensic sites do not contain DpnI sites. Secondly, Applicant's arguments are not persuasive because they are not directed to limitations recited in the claims since the claims are not limited to methods which analyze forensic nucleic acids or any particular type of nucleic acid that does not include a DpnI site. Nor are the claims limited to methods which specifically remove nucleic acids comprising STRs or which pre-treat nucleic acids in a manner that removes nucleic acids having STRs. There are no limitations in the present claims which distinguish the claims over the method of Satishchandran. Applicants are reminded that, although the claims are

interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Further, Applicants arguments are not convincing because the present claims specifically include removing/treating contaminating nucleic acids that are of bacterial origin (claims 15-18), and thereby nucleic acids that contain DpnI sites. As set forth by Satishchandran, DpnI cleaves GATC sequences if the adenine is methylated and the adenine nucleotide will be methylated if plasmid DNA is synthesized in Dam+ cells (col. 4, line 58 to col. 5, line 28). Thereby, the present claims clearly do not exclude the treatment of nucleic acids with DpnI in order to remove or inactivate contaminating nucleic acids.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634